H.R. 5006

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H.R. 4818 (PL 108-447) Conference Report

Committee Report (108-hr636)

Committee Report (108-sr345)

Office of the Secretary

Includes language directing that specific information requested from the chairmen on Labor, Health and Human Services, and Education, and Related Agencies, on scientific research or any other matter, be transmitted to the Committee on Appropriations in a prompt professional manner and within the time frame specified in the request.

The Committee rescinds the unobligated balance of funds appropriated in the Medicare Modernization Act for a facilities loan fund.

Includes language directing that specific information requested from the chairmen and ranking members of the Subcommittees and ranking members of the Subcommittees on Labor, Health and Human Services, and Education, and Related Agencies, on scientific research or any other matter, be transmitted to the Committee on Appropriations in a prompt professional manner and within the time frame specified in the request.

The Committee rescinds an appropriation provided in the Medicare Modernization Act for a facilities loan fund.

> The conference agreement provides \$1 M for the Secretary, working with IOM and relevant government agencies and non-profit entities, to study the delivery of psychosocial services to cancer patients and their families in the community setting. The report should include an analysis of: (1) the capacity of the current mental health and oncology provider system to deliver such care and the anticipated resources required nationwide; (2) available training programs for professionals providing psychosocial and mental health services; and (3) existing barriers to access to such care.

The conferees encourage and support the efforts of HHS agencies, including NCI and FDA, to keep pace with scientific discovery in the areas of nanotechnology, proteomics, and genomics, particularly as they apply to the prevention and early detection of cancer.

FISCAL YEAR 2004 APPROPRIATIONS REPORT LANGUAGE COMPARISON

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Office of the Director

Authorizes the Director of NIH with 1% transfer authority.

Authorizes the Director of NIH to collect third party payments for the cost of clinical services.

The Director my direct up to 1% of the total amount made available in this or any other Act to all National Institutes of Health appropriations to activities the Director may so designate. Congress must be immediately notified of the transfer

The NIH is authorized to collect third party payments for the cost of clinical services that are incurred in NIH research facilities and that such payments shall be credited to the NIH Management Fund. Funds shall remain available for 1 fiscal year after the fiscal year in which they are deposited.

A uniform percentage of the amounts appropriated in this Act to each Institute and Center may be utilized for the NIH Roadmap Initiative providing that the amount utilized shall not exceed \$176,800,000 without prior notification the to Committees on Appropriations of the House of Representatives and the Senate. The amounts from the Institutes and Centers shall be in addition to the amounts made available for the Roadmap Initiative from the Director's Discretionary Fund and to any amounts allocated to activities related to the Roadmap Initiative through the normal research priority-setting process of individual Institutes and Centers.

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The Director of the NIH may use funds available to enter into transactions (other than contracts, cooperative agreements, or grants) to carry out research in support of the NIH Roadmap Initiative of the Director. The Director may utilize such peer review procedures (including consultation with appropriate scientific experts) as the Director determines to be appropriate to obtain assessments of scientific and technical merit.

Ataxia-telangiectasia (A-T) - The Committee supports the development of an interinstitute coordinating committee for research on A-T comprised of representatives from all the institutes relevant to A-T, including NINDS, NICHD, NCI, NHGRI, NEI, NIA, and NHLBI. The coordinating committee should conduct workshops to identify important, unanswered scientific questions about A-T.

> Sepsis - The Committee encourages the Director to work with the NIAID, NHLBI and NCI in efforts to train providers on new sepsis treatment guidelines.

Lymphangioleiomyomatosis (LAM) - The Committee encourages NCI, ORD, NINDS, and NHLBI to explore opportunities for funding clinical treatment trials through both intramural and extramural means and to use all available mechanisms as appropriate.

NIH

Committee provides \$28,526,871,000 for the The Committee recommends 26 appropriations which together fund the \$28,900,300,000 for the NIH programs of the NIH.

The Conference agreement includes \$28,600,048 for the NIH

\$47,400,000 in the Public Health and Social Services Emergency Fund

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Biomedical Research and Development Price Index - The Committee has included sufficient funding to enable NIH to fully pay the committed levels on its grants. The funding level recommended by the Committee would permit the average cost of new and competing RPGs to rise by 2% instead of the 1% increase proposed in the budget request

Human Embryonic Stem Cell Research - The Committee strongly urges the administration to modify the current embryonic stem cell policy so that it provides this area of research the greatest opportunity to lead to treatment and cures. The Committee is deeply concerned with the slow pace of implementation of the current policy. The Committee was informed by NIH this year that anticipated spending on human embryonic stem cell research is just \$24,800,000.

Roadmap - The committee endorses support of the NIH Roadmap at a funding level of \$236,800,000 from funding contributed by the I/Cs based on less than 1% of their budgets and out of the Director's Discretionary Fund. The Committee expects to be notified on a quarterly basis in the contribution from the I/Cs or the allocation of funding by initiative changes from what is present in the congressional justification.

Biodefense - The Committee has not identified a specific funding level for biodefense research, choosing to give the Director of NIH flexibility in determining what share of NIH resources should be used.

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Balance - The committee holds the view that NIH should distribute funding on the basis of scientific opportunity. To enhance NIH's flexibility the Committee has attempted to minimize the amount of direction provided in the report accompanying the bill.

AIDS Funding - The Committee has chosen not to earmark a specific dollar amount for AIDS research. Funds should be spent in a manner fully consistent with the AIDS research plan developed by the Office of AIDS Research (OAR). The Committee has provided the Directors of OAR and NIH transfer authority to reallocate up to 3% of funds designated for AIDS research among the Institutes. The Committee encourages NIH to use this authority whenever it believes that an adjustment in the allocation of AIDS funding between Institutes is appropriate to achieve scientific objectives or to facilitate promising research efforts.

Conflict of Interest- The Committee supports the NIH proposals announced at the June 22 hearing of the House Energy and Commerce Health Subcommittee.

Consulting Fees - The Committee commends NIH for addressing the issue and commends the NIH director for convening a Blue Ribbon Panel to review and make recommendations regarding existing laws, regulations, policies and procedures governing consulting fees. The Committee was pleased to learn that the NIH plans to implement new regulations to ensure the integrity of its scientific research. The Committee directs the NIH Director to immediately put in place safeguards that will insure that no conflicts of interest exist between scientists and pharmaceutical and biotechnical companies, or any other entity.

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NCI

The Committee provides \$4,870,025,000 for The Committee recommends an the National Cancer Institute (NCI). The bill includes language requested by the Administration identifying up to \$8,000,000 for repairs and improvements to the NCI intramural facility in Frederick, MD.

appropriation of \$4,894,900,000 for the National Cancer Institute. The budget estimate includes funds to be transferred from the Office of AIDS Research.

The Conference Report gives NCI \$4,865,525,000. Up to \$8,000,000 may be used for facilities repairs and improvements at the NCI-Frederick Research and Development Center in Frederick, MD

American Russian Cancer Alliance - The Committee encourages NCI to establish a mechanism to support the continued development of this collaboration between the United States and Russian cancer researchers and to develop a plan to support the necessary infrastructure at U.S. institutions for the Alliance and its activities.

Angiogenesis - The Committee encourages NCI to continue to pursue efforts to establish greater collaboration between angiogenesis researchers in the fields of cancer biology and diabetes.

Angiogenesis - The Committee is encouraged by the progress made NHLBI and encourages closer collaboration with NCI in this area

> Anticancer compounds - The Committee encourages NCI to increase research in the area of anticancer compounds. The Committee understands that little research is conducted in this area and therefore urges the Institute to conduct appropriate research in this area.

Ataxia-telangiectasia [A-T] (OD) - The Committee supports the development of an inter-institute co-coordinating committee for research on A-T comprised of representatives from all institutes relevant to underlying causes of A-T with the goal of A-T, including but not limited to NINDS, NICHD, NCI, NHGRI, NEI, NIA and NHLBI.

Ataxia Telangiectasia [A-T] (NINDS) - The Committee encourages NINDS to work with the NCI and other appropriate Institutes to support research aimed at understanding the translating this basic research into treatments for the disease

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Basic Research on Pre-Disease Pathways (NIGMS) - The Committee encourages NIGMS to collaborate with other institutes including NCI, NIMH, and the Office of Behavioral and Social Sciences Research to fund research to integrate physiological knowledge of pre-disease pathways with behavioral studies.

Behavioral Research - The Committee sees NCI's behavioral science program as a model for other institutes.

NCI to develop a strategic plan to combat kidney cancer, including implementing the NCI PRG recommendations. The Committee Renal Cancers. NCI is urged to expand requests that NCI report in March 2005 on its progress in developing a strategic plan.

Kidney Cancer - The Committee encourages Bladder and Renal Cancer - The Committee is concerned about the poor implementation of the 2002 PRG report on Bladder and studies to improve detection and diagnosis of renal cancer. Also, NCI is urged to develop a novel treatment network to rapidly identify and test for new therapies for renal and bladder cancer in human patients and to expand studies on mechanisms of metastasis in these patients.

NCI to develop new strategies to accelerate the NCI to develop new strategies to the development of new blood cancer therapies, which might include, among other cancer therapies which might include, options, public-private partnerships, multidisciplinary collaborations, and multiinstitutional initiatives. NCI should consider flexible uses of current funding mechanisms in order to respond to the key recommendations of the blood cancer PRG. mechanisms in order to respond to the

Blood Cancers - The Committee encourages Blood Cancers - The Committee encourages accelerate the development of new blood among other options, public-private partnerships, multi-disciplinary collaborations, and multi-institutional initiatives. NCI is urged to consider flexible uses of current funding key recommendation of the blood cancer PRG.

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Bone metastasis study - NCI is encouraged Bone metastasis - NCI is encouraged to to develop an integrated approach to study cancer and bone biologists, clinical oncologists and metastasis experts and representatives from pharmaceutical industry. Key issues to address include the generation of novel models which mimic tumor/bone interaction and which delineate mechanisms to determine why tumor cells prefer bone for metastasis. NCI is urged to expand research on osteosarcoma to improve survival and quality of life and to prevent metastatic osteosarcoma for children and teenagers who develop this cancer.

develop an integrated approach to study bone metastasis, leveraging the expertise of bone metastasis, leveraging the expertise of cancer and bone biologists, clinical oncologists and metastasis experts and representatives from pharmaceutical industry. Key issues to address include the generation of novel models which mimic tumor/bone interaction and which delineate mechanisms to determine why tumor cells prefer bone for metastasis. NCI is urged to expand research on osteosarcoma to improve survival and quality of life and to prevent metastatic osteosarcoma for children and teenagers who develop this cancer.

> Brain Tumors (NINDS) - The Committee encourages NINDS to continue working with NCI to carry out the recommendations of the Report of the Brain Tumor Progress Review Group.

Brain Tumors - The Committee is concerned that insufficient attention is being given by NCI and NINDS to brain tumor research. The Committee encourages NCI to fund at least five Specialized Programs of Research Excellence in Brain Tumors (SPORE) grants in the upcoming fiscal year, with particular emphasis on those proposals which include both basic research and clinical treatment applications.

Cancer Centers - The Committee commends Cancer Centers and Minorities - The the Cancer Centers Program and encourages NCI to give consideration to the Program and encourages NCI to give establishment of a comprehensive center at consideration to the establishment of a a minority institution focused on research, treatment, and prevention of cancer in African American and other minority communities.

Committee commends the Cancer Centers comprehensive center at a minority institution focused on research, treatment. and prevention of cancer in African American and other minority communities.

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Cancer in Minority Communities (NCMHD) -The Committee encourages NCMHD to consider collaborating with NCRR and NCI in supporting the establishment of a cancer center at a historically minority institution focused on research, treatment and prevention of cancer in African American and other minority communities.

Cancer genomics - The Committee recommends that NCI continue to employ micro array technology to identify, characterize, and validate the gene pathways that cause cancer and that it continue to work cooperatively with public and private sector entities in this effort.

Cancer genomics - The Committee recommends that NCI continue to employ micro array technology to identify, characterize, and validate the gene pathways that cause cancer and that it continue to work cooperatively with public and private sector entities in this effort.

Cancer and Native Hawaiians - The Committee anticipates an update on the Director's task force to explore the continuing unique needs of the people of Hawaii and the Pacific Basin region.

Chronic Lymphocytic leukemia (CLL) - The Chronic Lymphocytic leukemia (CLL) - The Committee encourages NCI to strengthen research efforts into CLL. NCI is encouraged research into CLL, including improved funded through the CLL Research Consortium.

Committee urges the NCI to increase to enhance the scope of research activities therapies and their rapid movement from the laboratory to the bedside. The Committee STRONGLY urges the NCI to give favorable consideration to continuing and expanding the scope of research activities funded through the CLL Research Consortium.

> Complementary and Alternative Cancer Therapies - The Committee expects NCI to expand its work and its collaborative efforts with NCCAM to support research on promising complementary and alternative cancer therapies as well as on their integration with traditional therapies.

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Diethylstilbestrol (DES) - The Committee expects NCI to continue its support of research in this area, and to continue to consult with organizations representing individuals impacted by DES as they carry out DES research and education efforts.

Gynecological Cancers - The Committee expects the NCI to expand the number of gynecological cancers SPORES in the future. The Committee encourages continued research by the 4 ovarian SPORES that will lead to prevention and a better screening tool. The Committee supports the expansion of NCI's collaboration with NICHD for faculty development of gynecological oncologists.

Health Care Decision Making - The Committee applauds NCI's investment in staff and resources to help build the science of health care decision-making.

Hematology research (NIA) - The Committee Hematology Research (NIA) - The remains interested in advancing opportunities into blood disorders in the elderly population. The Committee is supportive of the ongoing collaboration between a voluntary organization and NIA, with participation of NHLBI, NCI and NIDDK, to develop a research agenda in this field. The Committee requests (from NIA) a report on the priority research areas identified in anemia in the elderly that offer promising clinical opportunities and the steps to be taken to accelerate research in these areas.

Committee is supportive of the ongoing collaboration between the American Society of Hematology and NIA, with the participation of NHLBI, NCI, and NIDDK, to develop a research agenda in this field.

Human embryonic stem cell research - The Committee requests NCI to submit a report to the Committee by December 1, 2004 listing the human embryonic stem cell research grants that NCI has awarded, the requests for proposals on human embryonic stem cell research that have been developed by NCI, and a plan describing how NCI will further develop its human embryonic stem cell research program.

> Imaging Systems Technology - NCI is urged to continue to take a leadership role with CMS and FDA to avoid duplicative reviews of new imaging technologies. The Committee continues to support NCI's increased emphasis on examining the molecular basis of disease through imaging technologies such as PET and MicroPET. The Committee encourages the large-scale testing of women for breast cancer and men for prostate cancer to demonstrate and quantify the increased diagnostic and staging capabilities of PET relative to conventional diagnostic and staging technologies.

Liver Cancer - The Committee encourages NCI to pursue the research initiatives that result from the Experts Conference convened in April 2004 in collaboration with convened in April 2004. NIDDK.

Liver Cancer - The Committee urges NCI to issue a Request for Applications based on the findings of the Experts Conference

Lung Cancer - The Committee encourages NCI to work with the thoracic surgical community to identify priority areas for new clinical and translational studies and to ensure their participation in any interdisciplinary research efforts.

Lymphangioleiomyomatosis (LAM) - The Committee understands that very recent scientific findings have presented new treatment approaches for clinical testing, and that experimental trials with the drug sirolimus have begun. The Committee encourages NCI, ORD, NINDS and NHLBI to explore opportunities for funding clinical treatment trials through both intramural and extramural means and to use all available mechanisms as appropriate, including support of state-of-the-science symposia and facilitating access to human tissues.

Lymphoma - The Committee encourages NCI to strengthen support for translational and clinical lymphoma research which can utilize laboratory discoveries in lymphoma biology. The Committee also encourages NCI to expand its commitment to investigation of the etiology and prevention of lymphoma. The Committee recommends that NCI evaluate its current investment in lymphoma clinical research and expand or initiate programs that would ensure support for translational and clinical research efforts.

> Molecular Cancer Diagnostics - NCI is encouraged to explore the use and clinical applications of molecular cancer diagnostics using circulating nucleic acids.

Multidisciplinary Research - NCI is encouraged to explore new opportunities with the Office of Behavioral and Social Sciences Research to increase the number of scientists who can bridge between behavioral/social science research and public health or biomedical research.

Myelodysplasia and myeloproliferative disorders research - The Committee encourages NCI and NHLBI to bring together encourages NCI and NHLBI to bring together scientific and clinical experts in these fields to explore collaborative and crosscutting research mechanisms to further this research agenda. The Committee urges NCI research agenda. The Committee urges to utilize the SEER program to collect data on the incidence and distribution of these diseases.

Myelodysplasia and myeloproliferative disorders research - The Committee scientific and clinical experts in these fields to explore collaborative and crosscutting research mechanisms to further this NCI to utilize the SEER program to collect data on the incidence and distribution of these diseases.

Myelodysplasia and myeloproliferative disorders (NHLBI) - The Committee scientific and clinical experts in this field to explore collaborative research and crosscutting mechanisms to further this research agenda.

Neurofibromatosis (NF) - The Committee encourages NCI to increase its NF research portfolio in such areas as further development of animal models, natural history studies, therapeutic experimentation, natural history studies, therapeutic and clinical trials.

Myelodysplasia and myeloproliferative disorders (NHLBI) - The Committee encourages NHLBI and NCI to bring together encourages NHLBI and NCI to bring together scientific and clinical experts in this field to explore collaborative research and crosscutting mechanisms to further this research agenda.

> Neurofibromatosis (NF) - The Committee encourages NCI to substantially increase its NF research portfolio in such areas as further development of animal models, experimentation, and clinical trials.

Nanosystems Biology - The Committee encourages NCI and the Office of the NIH Director to support a collaborative effort to bring together nanotechnology, systems biology and molecular imaging to examine the molecular basis of cancer.

Nanosystems Biology (OD) - the Committee urges the director, along with NCI, to support a collaborative effort to bring nanotechnology, systems biology and molecular imaging together to examine the molecular basis of cancer, consistent with the Director's Roadmap Initiative.

Pancreatic Cancer - The Committee is concerned that there are too few scientists researching pancreatic cancer. The Committee compliments the NCI's past efforts for increasing the research field through its program of a 50% formalized extended pay line for grants 100% relevant to pancreatic cancer. The Committee understands the NCI is adjusting this policy for the current year and looks forward to learning whether this revised approach is more successful in increasing the number or prostate cancer grants.

Pancreatic Cancer - The Committee urges NCI to maintain the 50% extended pay line for 100% relevant pancreatic cancer research grants as the best way to attract a critical mass of scientists to this field.

Pediatric Cancer - The conferees encouraged NCI to increase its support of dedicated translational research to accelerate the pace of pediatric clinical trials. The conferees also urge NCI to place a significant focus on genomic and proteomic approaches to identifying and validating potential molecular targets for therapeutic exploitation and evaluation in a controlled clinical trial setting. The Children's Oncology Group should be the dominant participant in this accelerated effort.

that NCI provide an annual update every January on its progress in prostate cancer research as it reflects the goals outlined in the plan for years FY04-08 ("Prostate Cancer Research Plan, FY2003-FY2008")

Prostate Cancer - The Committee requests Prostate Cancer - NCI is encouraged to continue supporting research to improve the accuracy of screening and early detection of prostate cancer.

> Psychoneuroimmunology and Cancer - The Committee is interested in NCI's initiative to evaluate the complex interrelationships among emotional, behavioral, neural and immunological processes and how they might affect the etiology and progression of cancer.

Radio Waves - The Committee urges NCI to support research using new noninvasive cancer targeting technique.

Saliva - The Committee encourages NIDCR to work cooperatively with NCI and other appropriate institutes in pursuing research initiatives on the development of saliva as a diagnostic tool.

Sepsis - To improve recognition of sepsis encourages the Office of the Director to work create and implement a program to train with a national alliance that is focused on sepsis education to create and implement a room doctors, critical care nurses, and program to train infectious disease physicians, emergency room doctors, critical to identify sepsis. The Committee further care nurses, and oncologists in the use of the new guidelines to identify sepsis. The Committee requests the support of NIAID, NHLBI and NCI in these provider education efforts.

Sepsis (OD) - The Committee urges the among health care providers, the Committee Director to work with outside organizations to infectious disease physicians, emergency oncologists in the use of the new guidelines encourages the Director to work with the NIAID, NHLBI, and NCI in these provider education efforts.

Social Work (NIMH) - The Committee commends the NIH Office of Behavioral and Social Science Research for its leadership in working together with NCI, NIAAA, NIA, NIDA, NIMH, NICHD.

Tobacco harm reduction - NCI is encouraged to expedite its research and review of existing literature regarding tobacco harm reduction. The Committee is particularly interested in what can be done from a public policy perspective to reduce tobacco related mortality and morbidity in that 10 - 15% of the adult population who cannot or will not quit smoking. The Committee encourages NCI to focus on the difference in harm caused by cigarettes vs. potential reduced exposure tobacco products and how effective these products could be in cessation efforts. NCI should consider exploring why Sweden has been so successful in reducing smoking and smoking related disease and what has been the impact of non-combustion products on smoking cessation in Sweden.

Tuberous Sclerosis complex (TSC) - The Committee encourages NCI to support programs examining the molecular and cellular basis of TSC, and the role of TSC in and cellular basis of TSC, and the role of tumor development.

Tuberous Sclerosis complex (TSC) - The Committee strongly encourages NCI to support programs examining the molecular TSC in tumor development.